

In the Specification:

Please amend various paragraphs to read as follows:

[0008] Also, while catheter assemblies typically are manufactured in standard sizes, such as 12 French, 14 [[,]] French, etc., patients come in many various shapes and sizes. Where a particular size catheter may be an optimum size for one patient, the surgeon may desire or require a different length of a subcutaneous tunnel for a different patient. However, the location of the catheter hub may dictate the length and/or location of the subcutaneous tunnel. It would be beneficial to provide a catheter assembly that has an adjustable location for the hub along the catheter assembly to provide the surgeon options for securing the catheter assembly to the patient.

[0009] Briefly, the present invention provides a multiple catheter assembly. The assembly includes a first catheter having a first proximal end region, a first distal end region terminating in a first distal tip, and an outer surface defining at least a first lumen extending longitudinally therethrough between a first distal and a first proximal opening. The assembly also includes a second catheter having a second proximal end region, a second distal end region terminating in a second distal tip, and a second outer surface defining at least a second lumen extending longitudinally therethrough between a second distal and a second proximal opening. The first lumen and the second ~~lumens~~ lumen are independent from each other for facilitating simultaneous flow in opposite directions. The outer surfaces of the first and second catheters are releasably joined for allowing the first and second distal tips and first and second proximal end regions to be at least partially longitudinally split from each other.

[0028] The invention as shown in this disclosure is preferably useful for the removal of blood [[,]] for purification from a blood vessel, such as the internal jugular vein, and introduction of purified blood into the same vessel. However, it will be known to those skilled in the art that the multiple catheter assembly 100 may be used to introduce or remove various fluids in various areas to be catheterized.

[0035] Referring back to Fig. 1, the distal tip of the first catheter 110 includes the first distal opening 118 extending therethrough. Likewise the distal tip 136 of the second catheter 130 includes the second distal opening 138 extending therethrough. Preferably, the distal tips 116, 136 are blunt, in that they are configured to lie generally in a plane which is perpendicular to the longitudinal length of the cannulating portion 102. The distal tips 116, 136 may have a semicircular cross section or a slightly circular cross section. However, in the present embodiment, referring to Figs. 3 and 4, the distal tips 116, 136 comprise a first distal generally oval cross section 117 and a second distal generally oval cross section 137. However, those skilled in the art will recognize that the distal tips 116, 136 may include cross sections of other ~~shaped~~ shapes, such as round, or other suitable shapes. Referring to Fig. 1, it is preferred that the distal tips 116, 136 have a distal transition portion 119, 139, respectively, wherein the cross section transitions from semi-circular, proximally of each distal transition portion 119, 139, to oval, distally of each distal transition portion 119, 139. A plurality of side apertures 194 are located throughout the first distal end region 114 and the second distal end region 134. Specifically, in the preferred embodiment, the plurality of side apertures 194 are located on the first and second generally oval cross sections 117, 137, respectively, although those skilled in the art will recognize that the side apertures may also or alternatively be located on the first and

second generally semi-circular cross-sections 128, 148 just proximal of each of the distal tips 116, 136. The side apertures 194 on the first semi-circular cross-section are in fluid communication with the first lumen 122 and the side apertures 194 on the second semi-circular cross-section are in fluid communication with the second lumen 142.

[0036] Still referring to Fig. 1, a longitudinally translatable hub 150 is releasably connected to the proximal regions 112, 132 of the first and second catheters 110, 130, respectively. A preferred hub 150 is disclosed in U.S. Patent Application Serial No. _____ (~~Attorney Docket No. MED-0063~~) 10/691,331, filed on even date, which is incorporated by reference herein in its entirety as though fully set forth, although those skilled in the art will recognize that other hub designs may be used, or that the hub 150 may be omitted in its entirety. The hub 150, as shown in ~~[[Figs]]~~ Figs. 1, 5, and 6, is operable between an open position and a closed position and has a distal end 152 and a proximal end 154. The hub 150 is designed to allow both of the catheters 110, 130 in the multiple catheter assembly 100 to enter the distal end 152 of the hub 150 together. A distal channel 155 runs longitudinally through the hub 150 to house the catheters 110, 130. At a predetermined point along the hub 150, the distal channel 155 branches out, from the single distal channel 155, near the distal end 152 of the hub 150, to a first proximal channel 158 and a second proximal channel 159 near the proximal end 154 of the hub 150. Each of the first proximal and second proximal channels 158, 159 houses one or more individual catheters 110, 130 but less ~~[[that]]~~ than the number of catheters housed by the distal channel 155. In the present embodiment, as shown in Figs. 1, 5, and 6, the distal end 152 of the hub 150 is designed to juxtapose the first catheter 110 and second catheter 130 against each other and the proximal end 154 of the hub 150 is designed to separate the first catheter 110 from the

second catheter 130. The hub 150 may also be slid longitudinally along the multiple catheter assembly 100. The distal channel 155 and the first and second proximal channels 158, 159 of the hub are sized so that the hub 150 may frictionally maintain its place on the multiple catheter assembly 100.

[0038] The hub 150 is releasably attachable to a patient. The hub 150 includes a plurality of suture wings 156 protruding therefrom, which may be releasably attached to a patient. The suture wings 156 protrude from the hub 150 on either side of the distal channel 155 as shown in Fig. 5. Four suture wings 156 are positioned on the top hub portion 160 and the bottom hub portion 162 such that when the hub 150 is in the closed position, the four suture wings 156 align to form two suture wing assemblies 157, shown in Fig. 1. In the present embodiment, the suture wing assemblies 157 are adjacent to the tabs 172 and recesses 174, but they may be located anywhere on the hub 150. With the suture wing assemblies 157 located in a position away from the hinge [[158]] 151, they can be used to assist in securing the hub 150 in the closed position. Furthermore, this invention anticipates other means for releasably attaching a hub 150 to a patient. Further, while two suture wing assemblies 157 are shown in Fig. 1, those skilled in the art will recognize that more or less than two suture wing assemblies 157 may be used.

[0045] An extension tube connector 204 extends from each male threaded connector portion 200. Each extension tube connector 204 is sized to be inserted into the proximal end openings 111, 131 of each of the first catheter 110 and the second catheter 130, respectively. A barb 205 may extend from the tube connector 204 to retain the proximal end

112, 132 of each of the first and second lumens 110, 130, although those skilled in the art will recognize that more than one barb 205 may be used, or that the barb 205 may be omitted in its entirety. A compression fitting 206 is disposed over the exterior of each catheter 110, 130 and over each extension tube connector 204. A female threaded connector portion 208 is disposed over each compression fitting 206 and is threadedly connected to each respective male threaded connector portion 200, securing each extension tube assembly 113, 133 to each respective catheter lumen 110, 130 and providing for fluid communication between the extension tube assemblies 113, 133 and each respective catheter lumen 110, 130.

[0046] Referring back to Fig. 1, a fabric cuff 125 is disposed on a portion of the exterior of the catheters 110, 130, preferably approximately halfway between the proximal end regions 112, 132 and the distal end regions 114, 134 of the catheters 110, 130. The portion of the catheter 110, 130 located distal of the cuff 125 are inserted into the patient through an incision during catheterization, and the portion of the catheters 110, 130, as well as the remaining portions of the catheter assembly 100, remain exterior of the incision. The cuff 125 provides a surface for the patient's skin to graft to the catheter assembly 100. Preferably, the cuff 125 is constructed from DACRON® polyester or some other, suitable, biocompatible fabric.

[0047] Preferably, the first and second catheters 110, 130 are constructed from a biocompatible polyurethane, such as TECOTHANE® or CARBOTHANE® polyurethane, although those skilled in the art will recognize that other materials, such as biocompatible plastics such as, for example, polyethylene, homopolymers and copolymers of vinyl acetate such as ethylene vinyl acetate copolymer, polyvinylchlorides, homopolymers and copolymers of

acrylates such as polymethylmethacrylate, polyethylmethacrylate, polymethacrylate, ethylene glycol dimethacrylate, ethylene dimethacrylate and hydroxymethyl methacrylate, polyurethanes, polyvinylpyrrolidone, 2-pyrrolidone, polyacrylonitrile butadiene, polycarbonates, polyamides, fluoropolymers such as homopolymers and copolymers of polytetrafluoroethylene and polyvinyl fluoride, polystyrenes, homopolymers and copolymers of styrene acrylonitrile, cellulose acetate, homopolymers and copolymers of acrylonitrile butadiene styrene, polymethylpentene, polysulfones, polyesters, polyimides, polyisobutylene, polymethylstyrene and other similar compounds known to those skilled in the art may be used. It should be understood that these possible biocompatible materials are included above for exemplary purposes and should not be construed as limiting. If a biocompatible polymeric material is used to form the first and second catheters 110, 130, it is most preferred that the polymeric material includes a polyurethane or a polyolefin polymeric material having a preferably soft durometer.

[0054] A catheter tunneling adapter 210, preferably similar to the catheter tunneling adapter shown in Fig. 13 and disclosed in U.S. Provisional Patent Application Serial No. ~~60/447,086, filed February 13, 2003~~ or U.S. Provisional Patent Application Serial No. ~~60/491,034, filed July 30, 2003~~ 10/736,365 filed December 15, 2003, is releasably connected to the proximal ends 111, 131 of the catheters 110, 130. Alternatively, an adapter such as the adapter disclosed in U.S. Provisional Patent Application Serial No. ~~60/495,077, filed July 17, 2003~~ 10/889,816 filed July 13, 2004 may be used. Preferably, an extension 211 extending from the first end 212 of the tunneling adapter 210 is inserted into each of the proximal ends 111, 131 of the catheters 110, 130 and a trocar 214 is connected to the second end 216 of the adapter 210. The trocar 214, the adapter 210, and catheters 110, 130 are pulled through the subcutaneous

tunnel 24 made by the pointed end 218 of the trocar 214. Once the catheters 110, 130 have been placed in the subcutaneous tunnel 24, and after the adapter 210 and trocar 214 have been removed, the catheters 110, 130 appear as shown in Fig. 11. The ingrowth cuff 125 is disposed within the subcutaneous tunnel 24. Over time, skin tissue forming the wall of the subcutaneous tunnel 24 will grow into the ingrowth cuff 125, securing the catheters 110, 130 in the subcutaneous tunnel 24.

[0056] Regarding the first extension tube assembly 113 and referring to Figs. 8 and 9, the first female threaded connector portion 208 is first slid over the exterior of the proximal end 111 of the first lumen 110. Next, the first compression fitting 206 is slid over the exterior of the proximal end 111 of the first lumen 110. Then, the first extension tube connector 204 is inserted into the proximal end 111 of the first catheter 110. The first female threaded connector portion 208 is threadingly connected to the first male threaded connector portion 200, such that the compression fitting 206 and the proximal end 111 of the first catheter 110 are securely retained between the first female threaded connector portion 208 and the first extension tube connector 204. The process is repeated for connecting the second extension tube assembly 133 to the second catheter 130.

[0057] [[To]] Now with reference to Figs. 5 and 6, to further ensure that the proximal catheter end regions 112, 134 remain secured in the subcutaneous area 16 of the body 14, the hub 150 is secured to the assembly 100 by placing the catheters 110, 130 into the bottom hub portion 162 such that the first transition portion 186 is disposed in the first proximal channel 158 and the second transition portion 188 is disposed in the second proximal channel 159, with a portion of

the first and second catheters 110, 130 distal of the first and second transition portions 158, 159 being disposed within the distal channel 155. The top hub portion 160 is pivoted about the hinge 151 to the closed position such that the tabs 172 on the top hub 160 portion snap into the recesses 174 in the bottom hub portion 162, securing the hub 150 to the catheters 110, 130. The hub 150 may now be sutured to the patient's skin by suturing the sutures (not shown) over the suture wing assemblies 157. Insertion of the catheter assembly 100 is now complete, as shown in Fig. 12.

[0059] After the catheter assembly 100 has been inserted into the patient for sufficient time for the ingrowth cuff 125 to become secured within the subcutaneous tunnel 24, the sutures may be cut from the suture wing assemblies 157. The hub 150 may be removed by unsnapping the tabs 172 in the top hub portion 160 from the recesses 174 in the bottom hub portion 162, pivoting the top hub portion 160 about the hinge 151 to open the hub 150, ~~[[are]]~~ and removing the hub 150 from the rest of the catheter assembly 100.

[0060] In an alternative insertion method, the ~~catheter~~ catheters 110, 130 are pulled through the subcutaneous tunnel 24 prior to inserting the distal ends 114, 124 of the catheters 110, 130 into the vessel being catheterized. In this method, the catheter tunneling adapter 210 is connected to the distal ends 114, 134 of the catheters 110, 130 and the pointed end 218 of the trocar 214 is used to form the subcutaneous tunnel 24 and to pull the catheter lumens 110, 130 through the tunnel 24. The pointed end 218 of the trocar 214 exits the skin proximate to the insertion site 20. The trocar 214 and the catheter tunneling adapter 210 are removed and the distal ends 214, 234 of the catheters 210, 230 are inserted into the incision 18 as described above.

The extension tube assemblies 113, 133 may be connected to the proximal ends 111, 131 of the catheters 110, 130 prior to or after inserting the catheters 110, 130 into the vessel.